FEB 1 5 2001

K004032

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the PERFECTA® and EXTEND® Femoral Stems.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 27, 2000
Contact Person:	Ehab M. Esmail Senior Regulatory Affairs Associate **Phone:** 901-867-4732 **Fax:** 901-867 4630
Proprietary Name:	**PERFECTA® and EXTEND®**
Common Name:	FEMORAL STEM
Classification Name and Reference:	21 CFR 888.3350 Hip joint metal/polymer semi-Constrained cemented prosthesis – Class II 21 CFR 888.3358 Hip joint metal/ polymer/ metal semi-constrained porous-coated uncemented prosthesis – Class II
Device Product Code and Panel Code:	Orthopedics/87/LPH/JDI

DEVICE INFORMATION

A. INTENDED USE

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,

RECEIVED DEC 29 9 44 AM '00 FDA/CDRH/OD/DMC

OR

SK3

5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The PERFECTA® and EXTEND® Femoral Stems (with new neck geometry and impaction dimple) are single use components.

B. DEVICE DESCRIPTION

The design features and functions for the PERFECTA® and EXTEND® Femoral Stems (with new neck geometry and impaction dimple) will be identical to the design features and functions for the currently available PERFECTA® and EXTEND® Femoral Stems with the exception of the new neck geometry and impaction dimple. The reduction in neck geometry will allow for an increased range of motion and reduce the likelihood of impingement of the neck and liner. The new dimple configuration will provide torsional control during implant insertion. All femoral stems will be available in a range of sizes, different types of stem surface treatment/coatings and will feature the same Wright Medical Technology (SLT) 12/14 taper. The function of the taper will not be affected by the new neck geometry.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the PERFECTA® and EXTEND® Femoral Stems (with new neck geometry and impaction dimple) are substantially equivalent to the currently available PERFECTA® and EXTEND® Femoral Stems. The safety and effectiveness of the PERFECTA® and EXTEND® Femoral Stems (with new neck geometry and impaction dimple) are adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2001

Mr. Ehab M. Esmail
Senior Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K004032
Trade Name: Perfecta and Extend Femoral Stems
Regulatory Class: II
Product Code: LPH and JDI
Dated: December 27, 2000
Received: Decemer 28, 2000

Dear Mr. Esmail:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

PERFECTA® and EXTEND® Femoral Stems

INDICATIONS STATEMENT

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity;
4) revision procedures where other treatments or devices have failed; and,
5) treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K004032

Prescription Use X
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

for Mark N. Milkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K004032